

REMARKS

Claims 16-21 and 23-25 have been cancelled in response to the rejection under the doctrine of obviousness type double patenting based on claims in copending application number 10/042,203.

Applicants maintain there is no basis for the rejection of claims 1-15 and 22 under 35 USC § 112, first paragraph. As set forth in the Office Action on the last two lines of page 2 and the first line of page 3, the specification is enabling for compounds "which do not have a OH or an -OC(O)C₁-C₄ alkyl." No basis has been given as to why the specification does not provide enablement for the claimed compounds, which do have such groups, or the claimed methods for using them.

With the structure of the claimed compounds identified, applicants submit one of ordinary skill in art could synthesize these compounds without undue experimentation relying only on conventional methods for synthesizing ureas. In addition to the conventional methods, the specification provides ample guidance to one skilled in the art as to how to prepare the claimed compounds. General preparative methods for synthesizing ureas are given on pages 15-19. One skilled in the art would recognize the appropriate starting materials (substituted anilines and substituted nitro-aryls) necessary to employ in these methods to arrive at the claimed compounds. Methods for preparing starting materials are well known (substituted anilines and substituted nitro-aryls) and publications, which describe such methods, are disclosed on page 15 of the specification and incorporated by reference. Additional guidance on the selection of starting materials and reaction conditions is provided by the general synthesis procedures provided on pages 26-62 and further guidance is provided by the specific examples described on pages 62-97. These specific examples do not include ureas with the required -OH or -OC(O)C₁-C₄ alkyl substituents of the claimed compounds; however, syntheses that prepare ureas having corresponding methoxy substituents and halogen substituents are illustrated. Based on the disclosure within the specification and conventional methods known in the art, one of ordinary skill in the art clearly would be able to prepare the claimed compounds without undue experimentation. No evidence has been presented to the contrary.

In addition, the specification provides ample guidance on how to prepare pharmaceutical compositions with the compounds of this invention and how to administer these compositions in the treatment of various conditions. See, e.g., pages 9-15. The

specification also provides dosage ranges for the various methods of administration (see page 14) and assays for determining the activity levels of the compounds. One of ordinary skill in the art by performing the same assays described in the specification or similar tests, can, by routine experimentation, determine the activity levels of each of the claimed compounds in treating the conditions identified in claim 22. This is absolutely routine in the field.

“T[h]e [enablement] requirement is satisfied if, given what they [those of ordinary skill in the art] already know, the specification teaches those in the art enough that they can make and use the claimed invention without ‘undue experimentation.’” See *Amgen v Hoechst Marion Roussel*, 314 F.2d 1313, 65 USPQ2d 1385 (Fed. Cir. 2003). Given the extent of the disclosure provided, it would at most involve routine experimentation, if any at all, for one of ordinary skill in the art to treat the conditions recited in claim 22 with a compound of this invention.

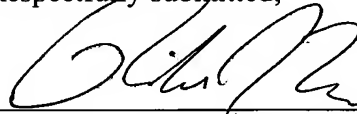
Even absent the specification disclosures discussed above, the rejection is clearly deficient in general under controlling case law. The courts have placed the burden upon the PTO to provide evidence shedding doubt on the disclosure that the invention can be made and used as stated; see, e.g., *In re Marzocchi*, 439 F.2d 220, 169 U.S.P.Q. 367 (CCPA 1971) (holding that how an enablement teaching is set forth, either by use of illustrative examples or by broad terminology, is of no importance.) The disclosure must be taken as in compliance with the enablement requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein. See *In re Marzocchi*, supra. No such evidence or reason for doubting Applicants’ disclosure has been provided. Only general statements and conclusions are made.

The Office action refers to the absence of working examples illustrating the claimed compounds to support the rejection. However, there is no requirement that applicants provide working examples relating to synthesis of the claimed compounds or their use to satisfy the statute. Instead, as discussed earlier, there is no requirement for any examples. See, for example, *Marzocchi*, supra, stating that how “an enabling teaching is set forth, either by use of illustrative examples or by broad terminology, is of no importance.” The MPEP also agrees by stating that “compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, does not turn on whether an example is disclosed.” See MPEP § 2164.02.

Applicants have provided more than adequate guidance to enable the claimed invention and the PTO has failed to establish otherwise. Thus, applicants submit the rejection under 35 USC § 112, first paragraph, should be withdrawn.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



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Attorney Docket No.: BAYER-0015-P04

Date: March 10, 2006